K033617

MAR - 1 2004

Attachment VI

510(k) Summary

Vasomedical, Incorporated
EECP® Therapy System Model TS4 with/without Pulse Oximetry
EECP® Therapy System Model TS3 with/without Pulse Oximetry
Enhanced External Counterpulsation Model MC-2

1. Date Prepared: 17 November 2003

2. Submitter's Name: and Address
Vasomedical, Inc.
180 Linden Ave.
Westbury, NY 11590

3. Contact Person:
Thomas R. Varricchione, MBA, RRT
Vice President, Clinical, Regulatory and Quality Affairs
Vasomedical, Incorporated
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4. Device Name:
EECP® Therapy System Model TS4 with/without Pulse Oximetry
EECP® Therapy System Model TS3 with/without Pulse Oximetry
Enhanced External Counterpulsation Model MC-2

Proprietary Names:
EECP® Therapy System Model TS4 with/without Pulse Oximetry
EECP® Therapy System Model TS3 with/without Pulse Oximetry

Enhanced External Counterpulsation Model MC-2
Common Name: Enhanced External Counterpulsation (EECP®) Therapy System
Classification Name: Device, Counter-pulsating, External

5. Predicate Device: The EECP® Therapy Systems listed above are substantially equivalent to the EECP® Therapy System Model TS3, Model TS3 with Pulse Oximetry, and Enhanced External Counterpuls-ation Model MC-2. FDA granted 510(k) clearance for the predicate device on June 14, 2002 (K020857, corrected letter issued June 18, 2002).

6. Device Description: Vasomedical's EECP Therapy System Model TS3, Model TS3 with Pulse Oximetry and Model MC-2 have been previously described to FDA. The EECP® Therapy System Model TS4 with/without Pulse Oximetery is comprised of three major components, a Control Console, a Treatment Table, and a patient Cuff Set.

The Control Console accommodates the air compressor and reservoir, a signal module panel, a power module, a microprocessor with touch screen/keyboard interface, data storage drives and printer, and components for acquiring and processing ECG, finger plethysmograph and oxygen saturation signals. The signals are obtained non-invasively. The microprocessor is used to operate and monitor the system by means of proprietary custom software, with the operator using the touch screen/keyboard interface to control its operation. The screen displays information pertinent to operating the system, as well as treatment parameters and patient waveforms during use. Treatment pressure is selected by the operator and then monitored and maintained automatically. The touch screen employs "hardware-less keys" which the operator touches to select a function or execute a command and the keyboard enables alphanumeric text entries. An internal hard disk drive is used to store data on the system a printer is used to produce hard copy of site and patient identification and physiologic data.

The Treatment Table incorporates a pneumatic circuit valve assembly and is set at a height convenient for both patient and operator use. The valve assembly consists of three pairs of inflation/deflation valves that open and close on command to inflate or deflate the patient Cuff Set with air. The valve assembly is connected to the air compressor and reservoir components in the Control Console via connecting air hoses.

The electrocardiogram of the patient is detected to initiate triggering of the inflation/deflation valves at appropriate times during the cardiac cycle. External pressure is applied via a patient Cuff Set to the lower extremities of the patient in synchronization with the resting, diastolic phase of the heart cycle, i.e. the cuffs compress vascular beds in the calves, lower thighs and upper thighs/buttocks on inflation. This pressure is applied sequentially from the calves, to the lower thighs, to the upper thighs and buttocks, forcing blood back to the heart, increasing coronary arterial perfusion pressure and coronary arterial blood flow (diastolic augmentation), as well as venous return to the right side of the heart. Immediately before the heart begins to eject blood during the next systolic phase, the cuffs are rapidly deflated and all externally applied pressure is eliminated. The vasculature in the lower extremities reconforms and is able to receive the output of the heart with lessened resistance, thereby reducing systolic pressure and the workload of the heart (decreased afterload).

Proposed changes to the to the labeled contraindications of EECP Therapy Systems are described in Attachment Ia, along with justification and supporting documentation in Attachments Ib through Ih.

7. Intended Use:

The EECP® devices listed in this 510(k) Premarket Notification (EECP® Therapy System Model TS4 with/ without Pulse Oximetry, Model TS3 with/without Pulse Oximetry, and Model MC-2) are non-invasive external counterpulsation devices intended for the use in the treatment of patients with stable or unstable angina, congestive heart failure, acute myocardial infarction, or cardiogenic shock.

8. Comparison of Technological Characteristics:

Technological and functional characteristics of the devices listed in this 510(k) Premarket Notification are essentially the same as those of the predicate devices. The devices listed in this 510(k) Premarket Notification are therefore substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 2004

Vasomedical, Inc.
c/o Thomas R. Varricchione, MBA, RRT
Vice President of Clinical, Regulatory and Quality Affairs
180 Linden Avenue
Westbury, NY 11590

Re: K033617
Trade Name: Vasomedical Enhanced External Counterpulsation (EECP®) Systems
Regulation Number: 21 CFR 870.5225
Regulation Name: External Counter-Pulsating Device
Regulatory Class: III (three)
Product Code: 74DRN
Dated: February 11, 2004
Received: February 12, 2004

Dear Mr. Varricchione:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033617

Device Name: Vasomedical Enhanced External Counterpulsation (EECP®) Systems

EECP® Therapy System Model TS4 with/without Pulse Oximetry
EECP® Therapy System Model TS3 with/without Pulse Oximetry
Enhanced External Counterpulsation Model MC-2

External Counter-pulsating Device

Indications for Use: Vasomedical, Inc.'s Enhanced External Counterpulsation (EECP®) Therapy Systems are non-invasive external counterpulsation devices intended for use in the treatment of patients with stable or unstable angina, congestive heart failure, acute myocardial infarction, or cardiogenic shock

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033617